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| 10/676,270 | 10/02/2003 | Hiroki Sakakibara | 7412/80657 | 3446 |

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| EXAMINER | |
|---|---|
| SAMALA, JAGADISHWAR RAO | |
| ART UNIT | PAPER NUMBER |
| 1618 | |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/676,270 | SAKAKIBARA ET AL. | |
| | Examiner | Art Unit | |
| | JAGADISHWAR R. SAMALA | 1618 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *21 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/05/2004; 10/30/2006; 10/31/2006&10/31/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### Status of Application

1. Acknowledgement is made of amendment filed on 11/21/2007. Upon entering the amendment, claims 1-9 are pending and presented for examination.

### Response to Arguments

2. Applicant's arguments filed on 11/21/2007 with respect to claims 1-9 have been fully considered but they are not persuasive. The 102(b) and 103(a) rejection is maintained and made **FINAL**.

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Naoki Nishimura et al. (Eur. J. Appl. Physiol. 87, 337, 2002).

Naoki discloses a vascularization therapy comprising steps of: immersing right forearm in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34 °C. The CO2 bathing was performed consecutively for five days. As a control study, subjects bathed in fresh water at 34 °C under the same conditions (see abstract). Tympanic temperature (T~) was significantly lowered during CO2 bathing, cutaneous blood flow in the immersed right forearm was significantly increased greatly, and during CO2 bathing reached 200-250% of the pre-bathing control value. The rate of increase

was greatest during the first 10 min of 002 bathing, and then tended to lessen (see page 339). And also the results of the study discloses that CO2 bathing produces a decline in core temperature, an increase in cutaneous blood flow, and an elevation of the score on thermal sensation. In CO2 bathing, increased cutaneous blood flow due to cutaneous vasodilation can facilitate the formation of new blood vessels of an affected site.

It is noted that the intended use "vascularizaiton " recited in the claims are considered, but the claims are properly included in this rejection because a recitation of the intended use of claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, and then it meets the claim.

Applicant's arguments filed on 11/21/2007 have been fully considered but they are not persuasive.

Applicant asserts that Nishimura does not teach or suggest the vasuclarization therapy claimed in the present invention.

This argument is not persuasive since Nishimura teaches the effects of repeated carbon dioxide-rich water bathing on core temperature, cutaneous blood flow and thermal sensation. These thermal effects of carbon dioxide bathing could be ascribed largely to the direct action of carbon dioxide on vascular smooth muscles and to the activity of thermoreceptors in the skin. Since Nishimura teaching includes same composition (carbonated warm water having close range of carbon dioxide concentration and temperature) indicates that carbon dioxide bathing increases

cutaneous blood flow due to cutaneous vasodilation, regardless of the causative mechanism/mechanism underlying this phenomenon, the carbon dioxide absorbed through the skin during bathing, the blood carbon dioxide concentration will be elevated and would facilitates the process of vascularization. Further, Nishimura specifically discloses that to attain long-lasting, stable effects of carbon dioxide for peripheral vascular diseases, carbon dioxide bathing is usually repeated. Hildebradt and Steinke examined the effects of 11 days of consecutive carbon dioxide bathing on peripheral circulatory resistance, and indicated that this parameter was improved as carbon dioxide bathing progressed (see pages 340-341). The same method, employing the same steps and same composition, must have the same effects.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ritter et al. (US 6,086,863) in view of Naoki Nishimura et al. (Eur. J. Appl. Physiol. 87, 337-342, 2002).

Ritter discloses a therapeutic composition comprising pharmacologic agents or biologics that accelerate the wound healing process (see abstract). Essentially, all wound healing involves the repair or replacement of damaged tissues including but not limited to skin, muscle, neurological tissues, bone, soft tissue, internal organs or vascular tissue (see column 1, lines 19-25, which would encompass "Vascularization therapy" as claimed). Most of basic research in angiogenesis has concentrated on the various steps involved in blood vessel growth and in identifying methods that either enhance or inhibit such processes. The therapeutic composition includes genetically engineered stromal cells (e.g. fibroblasts with or without other cells and/or elements found in loose connective tissue taken from the subject, including but not limited to, endothelial cells, pericytes, macrophages, monocytes, plasma cells, mast cells, adipocytes, etc) which express a gene product beneficial for successful and/or improved wound healing process. The therapeutic composition includes microspheres and one or more of agents selected from the group consisting of anti-inflammatory, antibiotic, antiseptic, antifungal, analgesic, astringent agent and collagen for healing the injured tissue (see column 4, lines.

Ritter meets the claim limitations as described above but fails to include carbonated warm water having a carbon dioxide concentration of at least 700 ppm in the therapeutic composition.

However, Naoki discloses a vascularization therapy comprising steps of: immersing right forearm in carbon dioxide-rich water (1,000 ppm) that was maintained at a temperature of 34 °C.

It would have been obvious to one of ordinary skill in the art to modify the therapeutic composition disclosed by Ritter to include carbonated warm water having a carbon dioxide concentration of at least 700 ppm, because Naoki teaches that carbonated warm water having high concentration of CO2 is useful in the formation of new blood vessels of an affected site, because the presence of CO2 at high concentration and warm temperature substantially increased cutaneous blood flow and thermal sensation and consequently increase the number of vascular endothelial cells in the tissue of an affected site.

Because carbonated spring water has been used for the treatment of peripheral vascular diseases, due to their potent vasodilation action, they are widely used for vascularization therapy; one of ordinary skill in the art would have motivated to incorporate the carbonated warm water in the composition advanced by Ritter. Based on the teaching of Naoki, there is a reasonable expectation of successfully preparing stable and effective therapeutic composition for the vascularization therapy, utilizing vasodilation action and increased blood flow volume brought about by carbonated warm water having carbon dioxide to increase the number of newly formed blood vessel at an affected site. In other words, the combination of the cited references provides sufficient information to make and use the invention as claimed.

Applicant's arguments filed on 11/21/2007 have been fully considered but they are not persuasive.

Applicant asserts that either Nishimura or Ritter teaches or suggests the vascularization therapy recited in the instant claims.

This argument is not persuasive since Ritter reference is combined for its teaching of knowledge in the art for wound healing and muscle regeneration both involves the repair of damaged tissues and replacement of missing tissue by applying the composition to wound, by dripping, spraying, painting, washing or by any other suitable method of topical application, while Nishimura reference shows an equivalence that is recognized in the art for vasodilation and vascularization as describe above. Therefore, the applicant has not set forth a persuasive argument that bars the prior art from being properly applied against the instant claims. The same method, employing the same steps and same composition, must have the same effects.

## Conclusion

1. No claims are allowed at this time.

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAGADISHWAR R. SAMALA whose telephone number is (571)272-9927. The examiner can normally be reached on 8.30 A.M to 5.00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Jagadishwar R Samala
Examiner
Art Unit 1618